CARDIOCOM®

EXPERTS IN TELEHEALTH℠

K122285

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510(k) Summary

AUG 14 2012

Submitter:	Cardiocom, LLC 7980 Century Boulevard, Chanhassen, MN 55317
Contact Person:	Daniel L. Cosentino, CEO, President, Cardiocom, LLC Phone: 888-243-8881 Fax: 888-320-8881
Date Prepared:	Tuesday, May 01, 2012
Trade Name:	Tablet Commander
Common Name	Remote Patient Monitoring System
Classification:	Name: Radiofrequency physiological signal transmitter and receiver Regulation: 21 CFR §870.2910 Panel: Cardiovascular Class: II
Product Code:	DRG
Predicate Device(s):	The subject device is equivalent to the following devices: Cardiocom Commander III, K053304; Intel Health Guide Express, K103276; Hommed Genesis Touch, K112858
Device Description:	The Tablet Commander is a software application. Once installed on a commercially-available device, the Tablet Commander software uses standard communication protocols to exchange information with other medical devices (peripherals). Data collected from the medical devices is transmitted back to a database for review by a caregiver. The Tablet Commander software has a user interface which allows the patient and caregiver to communicate using methods which include questions and answers.
Intended Use:	The Tablet Commander device is for use by patients to collect and transmit general health information, physiological measurements and other data between themselves and a caregiver. The Tablet Commander makes no diagnosis. Clinical judgment and experience are required to check and interpret the information transmitted. The Tablet Commander is not intended as a substitute for medical care.

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Table 1 – Intended Use Comparison with Predicate Devices

	Submission Device	Predicate #1 – K103276 – Intel Health Guide Express	Predicate #2- K112858-Honeywell Hommed Genesis Touch	Predicate #3- K053304- Commander III
Indications for Use	The Tablet Commander device is for use by patients to collect and transmit general health information, physiological measurements and other data between themselves and a caregiver. The Tablet Commander makes no diagnosis. Clinical judgment and experience are required to check and interpret the information transmitted. The Tablet Commander is not intended as a substitute for medical care.	The Intel Health Guide Express is intended to collect vital sign measurements from the physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys. The Intel Health Care Management Suite allows the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients. The Intel Health Guide Express is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The Intel Health Guide Express is	The Honeywell HomMed Genesis Touch Retrospective Physiological Monitoring System is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse oximetry, pulse rate, weight and manually entered temperature. The Genesis Touch Retrospective Physiological Monitoring System collects, displays and transmits vital signs measurements captured from commercially available FDA cleared wireless medical devices designed for home use. Collected measurement data from the Genesis Touch System can be transmitted via a communication module to a central viewing station where the data can be viewed and analyzed by a healthcare professional. The Genesis Touch Retrospective Physiological Monitoring System is intended for home use by adult and pediatric patients over twelve	The Commander III device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site. The Commander III makes no interpretation, evaluation, medical judgments, or recommendations for treatment. Clinical judgment and experience are required to check and interpret the information transmitted. The Tablet Commander is not intended as a substitute for medical care.

		contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.	years of age or in a healthcare related environment by healthcare providers. The Genesis Touch Retrospective Physiological Monitoring System is not intended for emergency use or real-time monitoring and does not have auditory or visual alarms for out-of-limit parameters.	

Table 2 – Technology Comparison with Predicate Devices

	Submission Device	Predicate #1 – K103276 – Intel Health Guide Express	Predicate #2-K112858- Honeywell Hommed Genesis Touch	Predicate #3- K053304- Commander III
Basic Technology Description	The Tablet Commander is a software application capable of running on any hardware platform that uses the Android operating system. The Tablet Commander interfaces with other electronics including FDA-cleared medical devices using standard wired and wireless protocols. Many Tablet Commanders then communicate that data to a back-end database application using the public telecommunications network.	The Intel Health Guide Express is a software application capable of running on any hardware platform that uses the Windows 7 operating system. The Intel Health Guide Express interfaces with other electronics including FDA-cleared medical devices using standard wired and wireless protocols. Many "Guides" then communicate that data to a back-end database application (Guide Virtual Care Suite) using the public telecommunications network.	The Honeywell HomMed Genesis Touch Retrospective Physiological Monitoring System is a software application running on a dedicated Commercially-Available Off-the-Shelf (COTS) tablet computer. The "Touch" interfaces with other electronics including FDA-cleared medical devices using standard wired and wireless protocols. Many "Guides" then communicate that data to a back-end database application (LifeStream Management Suite) using the public telecommunications network.	The Commander III is an electronic device consisting of a blood pressure system and built-in proprietary software which allows it to interface with other FDA-cleared medical devices. Many Commander III's then communicate that data to a back-end database application using the public telecommunications network.
Operating System	Android	Windows 7	Android	Proprietary firmware
Hardware Characteristics	Standard minimum requirements for mobile devices	Standard minimum requirements for mobile devices	Standard minimum requirements for mobile devices	LCD Display: 240 x 320 pixels CPU: Low speed Microcontroler Network connectivity:

				POTS or Cellular
Peripheral Interface Characteristics	The Tablet Commander interfaces with the peripheral medical devices using standard wired and wireless connections according to the protocols established by the manufacturer of the peripheral. The protocols include checksums with re-transmit and purge loops for data validation.	The Guide communicates with a variety of peripherals using standard wired and wireless technologies.	The Touch communicates with a variety of peripherals using standard wired and wireless technologies.	The Commander III is integrated with a blood pressure system and connected to other peripherals using RS232 serial connections according to protocols established by the manufacturer of the peripheral. The protocols include checksums with re-transmit and purge loops for data validation.

Functional and Safety Analysis:

Risk based verification and validation testing according to FDA guidances "Guidance for the Content of Premarket Submissions for software Contained in Medical Devices" and "General Principles of Software Validation" was completed to ensure the Tablet Commander functioned according to its requirements and specifications. Cardiocom used the voluntary standard IEC 62304 as a model for the software development environment to maintain quality throughout the software lifecycle. The Tablet Commander is identical to the tablet-based predicate devices in that the basic design principle is an application running on a commercial tablet. The data structuring and network communication design principles are identical to the predicate Commander III device. No new hazards to safety or effectiveness are presented by Tablet Commander, therefore, no clinical tests were conducted.

Conclusion:

Cardiocom considers the Tablet Commander to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 14 2012

Cardiocom LLC
c/o Mr. Mark Job (Regulatory Technology Services, LLC)
1394 25th Street NW
Buffalo, MN 55313

Re: K122285
Trade/Device Name: Tablet Commander
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver.
Regulatory Class: Class II (two)
Product Code: DRG
Dated: July 27, 2012
Received: July 30, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122285

Indications for Use

510(k) Number (if known): _____

Device Name: Tablet Commander

Indications For Use:

The Tablet Commander device is for use by patients to collect and transmit general health information, physiological measurements and other data between themselves and a caregiver.

Contraindications, Precautions, and Warnings:
The Tablet Commander makes no diagnosis. Clinical judgment and experience are required to check and interpret the information transmitted. The Tablet Commander is not intended as a substitute for medical care.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122285